IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DAWN GRAY, *Plaintiff* v. MAIN LINE HOSPITALS, INC., *Defendant*	Case: 2:23-cv-00263-KNS

DEFENDANT'S BRIEF IN SUPPORT OF ITS MOTION TO EXCLUDE PLAINTIFF'S EXPERT OPINIONS

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I. INTRODUCTION

Plaintiff, Dawn Gray, was a nurse in the Emergency Department at Paoli Hospital, which is part of the Main Line Health (MLH) system. In August of 2021, MLH implemented a COVID-19 Vaccination Policy ("Policy"), which required employees get vaccinated against COVID unless they were approved for a medical or religious exemption. Plaintiff submitted a request for a religious exemption from the Policy. In her exemption request, Plaintiff objected to genetic components in the COVID vaccine, and her pastor submitted a statement on her behalf, asserting that Plaintiff believed that the vaccine would alter the genetic make up of her body. The Religious Exemption Committee determined that COVID vaccines did not alter one's genetic makeup, and regardless of the accuracy of Plaintiff's statements about genetics, her exemption request was focused on science, rather than explaining her religious opposition to the vaccine. Plaintiff has filed claims under Title VII of the Civil Rights Act of 1964 and Pennsylvania Human Relations Act.

Plaintiff has obtained experts ostensibly in support of her claims and in response to Defendant's undue hardship defense.[1] Specifically, Plaintiff has provided two reports of proffered opinion testimony: (1) The report of Akram Boutros, MD (Exhibit A) ostensibly in support of her affirmative claims and to rebut the report of Defendant's expert, Daniel Salmon, Ph.D., a vaccinologist with Johns Hopkins (Ex. B); and (2) The report of Peter McCullough (Ex. C) which also purports to rebut Dr. Salmon's analysis.

[1] On October 2, 2023, Defendant filed a Motion for Summary Judgment seeking that this Court rule as a matter of law given that (a) Plaintiff's vaccination exemption request was based on personal/medical beliefs as opposed to religious beliefs, and (b) that there was an undue hardship in relation to granting an exemption to a nurse from a vaccination requirement under the Policy during a pandemic. (ECF Doc. No. 21). As Plaintiff's experts' reports and opinions are not reliable or helpful and should be stricken under Daubert, Defendant believes that the lack of admissible expert opinion serves to support this Motion for Summary Judgment.

As discussed herein, neither Dr. Boutros' initial report nor Dr. McCullough's rebuttal report are relevant; nor do they satisfy the *Daubert* standards of qualification, reliability, or fit. Moreover, the expert opinions underscore that Plaintiff's concerns are scientific in nature rather than religious.

II. LEGAL ARGUMENT

A. The Daubert Standard

Federal Rule of Evidence 702 allows a witness who is "qualified as an expert by knowledge, skill, experience, training or education" to offer opinion testimony if the proponent of such testimony demonstrates to the court that it is more likely than not that "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue…."[2] In *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 588 (1993), the Supreme Court further defined the Rule 702 standard as follows:

> The subject of an expert's testimony must be "scientific ... knowledge." The adjective "scientific" implies a grounding in the methods and procedures of science. Similarly, the word "knowledge" connotes more than subjective belief or unsupported speculation. The term "applies to any body of known facts or to any body of ideas inferred from such facts or accepted as truths on good grounds."

Daubert, 509 U.S. at 589–90 (citations omitted). Following *Daubert*, the Third Circuit has stated "Rule 702 has three major requirements: (1) the proffered witness must be an expert, *i.e.*, must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008). In other words, the expert must meet three criteria: qualifications, reliability, and fit. *Karlo v. Pittsburgh Glass Works, LLC*, 849 F.3d 61, 80 (3d Cir.

[2] Federal Rule of Civil Procedure 702 was amended as of December 1, 2023 mainly to clarify and emphasize that Plaintiff has the burden of establishing the admissibility requirements of the rule by a preponderance of evidence. Fed.R.Civ.Pro. 702, Advisory Committee Note, 2023 Amendments.

2017). In determining whether expert evidence is admissible, "the district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury." *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (*citation omitted*). Indeed, since *Daubert*, the Supreme Court has elaborated upon these principles, emphasizing the broad discretion district courts possess in fulfilling their gatekeeping role. *See, e.g., Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146–47, 118 S. Ct. 512, 519 (1997)("it was within the District Court's discretion to conclude that the studies upon which the experts relied were not sufficient. . . to support their conclusions).

Regarding reliability, the trial court must ensure that expert evidence is not only relevant, but also reliable. *Kannankeril v. Terminix Intern., Inc.*, 128 F.3d 802, 806 (3d Cir. 1997) (*citing Daubert*, 509 U.S. at 589). "[T]he reliability analysis applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, the link between the facts and the conclusion." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999). In assessing reliability of a proposed expert's testimony, courts consider:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 fn. 8 (3d Cir. 1994). The party offering the expert's testimony carries the burden to establish admissibility by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 418 (3d Cir. 1999).

With respect to the "fit" requirement, Rule 702 requires an "expert's scientific, technical, or other specialized knowledge ... help the trier of fact to understand the evidence or to determine

a fact in issue." Fed. R. Evid. 702(a). Thus, expert testimony must be "sufficiently tied to the facts of the case [such] that it will aid the [factfinder] in resolving a factual dispute." *U.S. v. Schiff*, 602 F.3d 152, 173 (3d Cir. 2010). Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *United States v. Xue,* 597 F. Supp. 3d 759, 766 (E.D. Pa. 2022).

B. The Report of Dr. Akram Boutros should be stricken under *Daubert* and Relevance Standards

a. Dr. Boutros' opinions in support of Plaintiff's affirmative claims should be stricken

Plaintiff submitted the report of Dr. Akram Boutros (Ex. A), which states that he was engaged "to provide opinions" on Dawn Gray's "Religious Exemption Request" as well as to rebut the expert report of Defendant's expert, Daniel Salmon (Exhibit B). As discussed below, Dr. Boutros has offered opinion testimony on religious issues for which he lacks any qualifications. Further, Dr. Boutros' selective cherry-picking of testimony and commentary on the evidence is not relevant or admissible. Further, to the extent Dr. Boutros offers opinions, they are not supported by the requirements of Federal Rule Civil Procedure 702 or *Daubert* as they lack any data or indicia of reliability. Additionally, as Dr. Boutros' opinions (outside his own *ipse dixit* or anecdotal experience) are epidemiological in nature, he is not qualified as an epidemiologist nor does he present any reliable support for the opinions and therefore they must be stricken. As the Supreme Court has said, "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Gen. Elec. v. Joiner*, *supra*, 522 U.S. at 146, 118 S.Ct. at 519.

Initially, Dr. Boutros engages in a commentary of the evidence based on his review of Dr. Gray's deposition transcript and exemption request.[3] Among other things, he offers opinions on the nature of her religious beliefs. Dr. Boutros is an internist and former executive of MetroHealth System. He is not qualified to comment on the evidence as he is offering no specialized knowledge and much of his report contains irrelevant information which does not fit the case. "[A]n expert cannot weigh contradictory evidence and place his imprimatur upon a particular version." *Kozak v. Struth,*, 515 Pa. 554, 531 A.2d 420, 421-22 (1987). Further, to qualify a witness to testify as an expert, Rule 702 requires the witness to have "specialized knowledge" regarding the area of testimony. *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998). Although the qualification prong of *Daubert* is liberally construed, a "proffered expert witness ... must possess skill or knowledge greater than the average layman...." *Aloe Coal Co. v. Clark Equip. Co.*, 816 F.2d 110, 114 (3d Cir.1987). Any comments on Plaintiff's religious beliefs offered by Dr. Boutros should be stricken because he is not qualified to speak on such matters, they are not relevant and his testimony is not helpful to a jury.

Other than comments about religious beliefs, Dr. Boutros does not offer any admissible opinions in support of Plaintiff's affirmative claims. Dr. Boutros opines without any data or underlining facts about various items which require epidemiological data, methodology and support. He has none. For example, he opines that in September of 2021 it was clear that institutions that allowed a larger number of exemptions did not experience larger number of staff

[3] By way of example, Dr. Boutros initially offers that Plaintiff has a polyethelene glycol (PEG) allergy which is itself reason for a COVID vaccine exemption. (Ex. A at p. 2). He further discusses PEG and its packaging in the vaccine. This opinion is not either relevant or helpful to the jury. Plaintiff has not filed claims of disability discrimination. Dr. Boutros also states that religious beliefs are hard for businesses to evaluate. This is not an expert opinion based on specialized knowledge that would be helpful to a jury.

or community infections. It is completely unknown from what source Dr. Boutros obtains this information as he does not provide data or citations to literature. Thus, it should be excluded.

Accordingly, Dr. Boutros' scant opinions in relation to Plaintiff's affirmative claims do not meet the Daubert or Rule 702 admissibility standards. They are not supported by data or any other scientific methodology to be admissible and should be stricken.

b. Dr. Boutros Does Not Offer Qualified or Reliable Opinions in Response to Dr. Salmon

Dr. Boutros purports to respond to the report of Dr. Daniel Salmon, a vaccinologist who provided a report with cites to detailed literature in support of his assertions. Dr. Boutros is not a vaccinologist. He is not an immunologist. His CV shows that he has most recently served as a healthcare executive. His opinions which are contrary Dr. Salmon do not cite any basis, methodology, or data. Accordingly, Defendant asks this Court to serve in its gatekeeper function to exclude such opinions.

Initially, Dr. Boutros agrees with Dr. Salmon that "COVID-19 posed a direct threat to patients and staff in health care facilities" and that health care facilities around the world were overwhelmed by COVID-19. (*Id.* at p. 5). He claims, however, that Dr. Salmon states that the goal of mandatory vaccination is to achieve herd immunity, which is absolutely not true. (*Id*.). The MLH COVID-19 Vaccination Policy was expressly designed "to protect patients, employees, students, volunteers, and members of the Medical Staff from COVID-19 infection through vaccination." (See ECF Doc. No. 21-3, at p. 129 for MLH COVID Vaccination Policy.).

Dr. Boutros further states that the MetroHealth System "permitted both medical and religious exemptions, and achieved similar lower rates of staff COVID-19 infections to hospitals and health systems that permitted very few exemptions." (Ex. A at p. 5.). Dr. Boutros is not clear in what he is comparing and offers no supporting basis for the statement. He does not identify

what percentage of infections ("low rates of infections") amounts to or how that compares to other health systems across the country or any data for comparison purposes. Again, it appears he is trying to make an epidemiological conclusion, but offers no evidence or support for the proposition. *See Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007) (striking expert opinion "that could not point to any epidemiological data supporting his opinion").

Dr. Boutros further agrees with Dr. Salmon that mandatory vaccination policies had a mixed impact on vaccine hesitancy and that most healthcare workers would support or acquiesce to the policy. (*Id.* at p. 6). He agrees with Dr. Salmon that "unvaccinated persons are at increased risk of contracting disease and transmitting disease to others." (*Id.*). He claims that the reasons for being unvaccinated is irrelevant because there would be the same amount of transmissibility regardless of the reason. (*Id.*).

Dr. Boutros agrees with Dr. Salmon that "the greater number of exemptions the higher the risk of infections and transmission." (Ex. A at p. 7). He further agrees that "health care institutions had a responsibility to limit religious exemptions to those with sincerely held beliefs that precluded vaccination in order to protect their staff and patients." (*Id*. at 7). He states that the concern is "most profound" when exemptions constitute a meaningful percentage of the staff. He believes that staff could leave faced with having to vaccinate but offers no support for this opinion with data or methodology.

As to alternative infection controls, Dr. Boutros said that their use did not pose additional risk to patients, staff or the community. (*Id.* at p. 10). Again, he offers no epidemiological data for this epidemiological opinion but, rather, offers his own anecdotal experience as a former CEO of a health system. Dr. Boutros is not aware of studies that differentiated between COVID-19 infection rates at healthcare institutions that issued larger exemption rates versus those that issued

smaller numbers of exemptions.[4] (*Id*. at p. 8). He claims that vaccinated staff were less compliant with masking, handwashing, and social distancing but offers no data or basis for the assertion. (*Id.*). Again, it is unclear where Dr. Boutros is coming up with his epidemiological opinions. Given that there is no support for his conclusions on whether the alternative controls posed an additional risk, they should be stricken in their entirety under *Daubert*.

Dr. Boutros also cited the mandate from the Centers for Medicaid and Medicare Services (CMS), which allows for accommodations where "legally required." Specifically, it states that "[w]hile accommodations could be appropriate under certain limited circumstances, no accommodation should be provided for staff that is not legally required." (*Id.* at p. 9). Dr. Boutros states his disagreement with Dr. Jonathan Stallkamp (Chief Medical Officer for MLH) about a robust policy mandate because he believes that a mandate increases the risk to the community "by reducing the number of healthcare professionals available to care for a community…". (*Id.* at p. 10). Again, Dr. Boutros does not cite to any study or information supporting this concern. On page 10 of his report, he disagrees with Dr. Stallkamp that exemptions to the mandate give rise to "significant … operational hardships" despite his previous agreement with Dr. Salmon's opinion in that regard. He does not provide any basis for this opinion, any methodology for it, other than what he believes responsible healthcare executives hold as factual.

As there is no scientific support for Dr. Boutros' opinions, they fail under *Daubert.* That is, most of his opinions are epidemiological in nature, and yet, he offers no reference to epidemiological studies or data. *See Gen. Elec. v. Joiner*, *supra*, 522 U.S. at 146; *Ervin v. Johnson*

[4] While there are no such studies on hospitals, it is a logical corollary given that unvaccinated individuals increase the risk of infection (as Dr. Boutros agreed), that a lower number of unvaccinated workers, the less risk there is to staff and patients. Indeed, there are studies that show that the higher vaccination rates for nursing home staff resulted in less COVID infections among staff and residents. *See, e.g.*, Soham Sinha & R. Tamara Konetzka, Association of COVID-19 Vaccination Rates of Staff and COVID-19 Illness and Death Among Residents and Staff in US Nursing Homes, 5 JAMA NETW OPEN 12, e2249002 (Dec. 29, 2022), doi:10.1001/jamanetworkopen.2022.49002.

& Johnson, Inc., 492 F.3d at 904. He provides no analytical support for his opinions. Dr. Boutros is not an epidemiologist. He is an internist doctor and healthcare administrator. While Dr. Boutros agrees at times with Defendant's experts, when he disagrees, he offers no evidence, no citations to literature, no basis for his decision. Accordingly, Dr. Boutros' rebuttal report should be stricken under *Daubert's* standards of qualification, reliability and fit. That is, he is not a qualified epidemiologist, he does not provide any reliable support for his conclusions and his opinions are, at best, anecdotal in nature.

C. The Report of Dr. Peter McCullough should also be stricken under *Daubert* and Relevance Standards

Plaintiff further produced a rebuttal report from Dr. Peter McCullough, (Ex. C) ostensibly in rebuttal to the report by defense expert, Dr. Daniel Salmon, although, as discussed herein, his report goes well beyond a rebuttal to Dr. Salmon. (Ex. B). As set forth below, Dr. McCullough's opinions in the rebuttal report do not meet qualification, reliability, or fit standards.

With regard to qualification, almost all of the report is a discussion of COVID-19 during the pandemic, vaccination requirements, and Dr. McCullough's opinions on how the pandemic could have been handled differently. Dr. McCullough is currently a Board certified Internist and Cardiologist. Dr. McCullough also has a Master's degree in Public Health with a focus in Epidemiology, but, as has been recognized and is evident from his CV, "his practice was almost entirely internal medicine and clinical cardiology until he began publishing on COVID-19 in the early days of the pandemic." *Navy SEAL 1 v. Austin*, 600 F.Supp.3d 1, 16 (D.D.C. 2022) (*quoted* in *Roth v. Austin*, 603 F.Supp.3d 741, 774 (D.Neb. 2022). As the *Roth* court recognized:

> Not only is it doubtful that Dr. McCullough's credentials demonstrate he is an expert on COVID-19, Dr. McCullough makes several claims that are outside the conclusions of the mainstream of the vast scientific studies of the COVID-19 virus and COVID-19 vaccination.

Roth, supra, 603 F.Supp.3d at 774. Indeed, during the COVID pandemic, Dr. McCullough became very active in voicing public opinions against the COVID-19 vaccines online and in social media. Publicly, his varied opinions (many of which railed against the use of COVID vaccines) have been criticized and debunked by numerous scientific sources, with entire websites dedicated to his questionable statements. *See e.g.*, Health Feedback, Reviews of Articles by Peter McCullough https://healthfeedback.org/authors/peter-mccullough. *See also* Dorit R. Reiss, *Misinformation and Covid-19*, 63 Santa Clara L. Rev. 147, 149–50 (2022)(stating "McCullough has become part of the anti-vaccine effort, speaking at anti-vaccine rallies and making statements against vaccines. His claims reflect the common anti-vaccine talking point addressed in this article: vaccines do not work but there are alternatives to them.") As set forth below, Dr. McCullough's reports are not scientifically reliable nor do they fit the case or his qualifications.

1. Overview of Dr. McCullough's September 2023 report

Dr. McCullough's 72-page report is filled with generalizations and snippets in time that have no relevance to this matter and should be excluded under basic relevance considerations. That aside, at the outset, Dr. McCullough states the reason for his report.

> I have been requested to provide expert rebuttal to the opinions of Drs. Daniel Salmon, Brett Gilbert, and Jonathan Stallkamp. I have also reviewed Mrs. Gray's religious exemption request, deposition transcript, and Main Line Health's criteria for considering an exemption request. The report will begin with general information about what was known about the science of COVID-19 at the time that Main Line Health instituted its policy and then address the comments made by the above individuals in their reports.

(Exhibit D at 5-6). Dr. McCullough then offers opinions about (1) the pandemic in general and efforts to combat COVID-19 (and how health authorities and health experts were wrong), (2) the lack of justification (in Dr. McCullough's opinion) for the MLH COVID-19 Vaccination Policy, (3) how COVID-19 vaccinations constituted "gene therapy" in Dr. McCullough's opinion and thus

triggered Mrs. Gray's religious beliefs, and (4) a summary of counterpoints to Dr. Salmon. As discussed below, Dr. McCullough is not qualified to opine on religious beliefs or the regulatory treatment of COVID vaccines. The opinions he offers are outside of his area of expertise, are unreliable, in contrast to authorities whom this Court may follow or defer, and they do not "fit" the affirmative claims of Plaintiff in this case.

2. Dr. McCullough's other opinions in the September 2023 report should be stricken under Daubert.

Dr. McCullough's report follows a pattern in which he exaggerates the risks of COVID vaccines and downplays the benefits. This may result in public attention on social media, but it does not withstand scientific scrutiny and therefore should not pass the Court's gatekeeping role under *Daubert*. His opinions regarding the vaccine are not based upon credible methodology, nor do they "fit" in this case as they do not assist in the determination of any relevant fact. Notably, his anti-vaccination comments are not relevant because Defendant and other healthcare institutions were required by the Center for Medicare & Medicaid Services (CMS), to implement vaccine mandates. That CMS mandate was upheld by the United States Supreme Court in *Biden v. Missouri*, 595 U.S. 87, 142 S. Ct. 647 (2022). It would be illogical and absurd to admit into evidence Dr. McCullough's opinion and purported studies of non-vaccine COVID-19 protocol when the CMS mandated Defendant to require vaccination.

3. McCullough's selective history of the pandemic and beliefs about herd immunity are not reliable opinions for a jury

Dr. McCullough concocts a history on the pandemic based largely on media reports, such as *Yahoo! News*. Dr. McCullough relies on these non-scientific articles to suggest that the pandemic was likely to become endemic in October 2021, right before a significant surge of Covid-19 cases in December 2021. Dr. McCullough apparently relies on these media reports to justify

his unsupported hypothesis regarding "herd immunity." Dr. McCullough's purported methodology on herd immunity does not meet the "reliability" or "fit" tests. He proposes, without explanation, a formula for herd immunity extracted from his alleged research. He does not define his research nor does he explain how COVID-19 fits into the purported formula. It is noted that the World Health Organization specifically cautioned against reliance upon herd immunity with regard to COVID-19 given the unknown variables. *See* Coronavirus disease (COVID-19): Herd immunity, lockdowns and COVID-19, December 31, 2020, https://www.who.int/news-room/questions-and-answers/item/herd-immunity-lockdowns-and-covid-19. Moreover, Dr. McCullough's speculation as to herd immunity is not pertinent to any relevant issue in this case.

In addressing constitutional challenges to vaccine mandates, Courts have regularly deferred to public health agencies. *Jacobson v. Massachusetts*, 197 U.S. 11, 25 S.Ct. 358 (1905) (stating "[i]t is no part of the function of a court or a jury to determine which one of two modes was likely to be the most effective for the protection of the public against disease.") Specifically with regard to natural or herd immunity, Courts have noted "even if there is vigorous ongoing discussion about the effectiveness of natural immunity, it is rational for [Defendant] to rely on present federal and state guidance in creating its vaccine mandate." *Norris v. Stanley*, 567 F.Supp.3d 818, 823 (W.D.Mich. 2021)(further noting "disputes over the most reliable science" are of "no moment" given the deference to public guidance). Defendant, and this Court, are certainly entitled to rely upon the information provided by the public health agencies such as the CDC and the FDA in making decisions related to vaccination and vaccine mandates during a worldwide pandemic, particularly given that Defendant was subject to the CMS mandate. Dr. McCullough's opinions regarding the efficacy of the Covid-19 vaccine and/or herd or natural immunity are of no relevance.

4. Dr. McCullough's opinions on Symptomatic vs. Asymptomatic spread do not provide a reliable measure for a jury

Dr. McCullough opines that asymptomatic spread of COVID-19 is trivial. He provides two sources for his views. One is a 2009 study relating to asymptomatic infection of influenza, a different virus. The other is Zachary J. Madewell et al., Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis, 3 JAMA Netw Open e2031756 (2020). Dr. McCullough postulates that this study on Household Transmission of COVID (for which he does not provide an APA style citation with the date of the article but rather, a misleading "last visited" date) supports that asymptomatic COVID-19 spread was negligible at 0.7%. This is not a responsible conclusion from the study. The 2020 meta-analysis gathered information from other studies and looked solely at household transmission rates. The studies upon which this metanalysis based its data had significant limitations (as many of the underlying studies did not look at asymptomatic cases) and the study did not draw any firm conclusions based on asymptomatic or pre-symptomatic transmissions. Furthermore, it appears that Dr. McCullough isolates asymptomatic numbers rather than combining them with presymptomatic numbers. Asymptomatic persons are those who never develop symptoms. Presymptomatic persons are those who have been infected with COVID but have yet to show symptoms. The study highlighted that "presymptomatic transmission does occur, with some studies reporting the timing of peak infectiousness at approximately the period of symptom onset." *Id.* Both asymptomatic and presymptomatic transmission present problems because the disease is transmissible without symptoms showing[5] and studies show infectiousness peaks right at the start of symptoms before isolation can occur. According to the Centers for Disease Control:

[5] Indeed, the literature supports that about 65% of transmission occurs before symptoms develop. Hart WS, Maini PK, Thompson RN. High infectiousness immediately before COVID-19 symptom onset highlights the importance of

> People infected with SARS-CoV-2 can transmit the virus even if they are asymptomatic or presymptomatic. Peak transmissibility appears to occur early during the infectious period (prior to symptom onset until a few days after), but infected persons can shed infectious virus up to 10 days following infection.[6]

Accordingly, the CDC recommended, among other things, staying up to date on COVID vaccinations. *See* CDC *supra* fn 6. Again, the Defendant (and the Court) are entitled to rely on the regulatory agencies such as the CDC which closely followed the pandemic and research. As a result of Dr. McCullough's contrary inferences from a very limited pool of data, he concludes that individuals with symptoms should simply isolate themselves, broadly suggesting that other COVID-19 policies and infection control measures such as vaccination are not necessary. While one might have wished for such a simple solution to the pandemic, the health authorities and prevailing science at the time was to the contrary.

Dr. McCullough is not an infectious disease doctor or a vaccinologist. His opinion that asymptomatic spread did not occur is drawn from a metanalysis and other reports published early in the pandemic and derives conclusions that the authors of those studies did not make. Finally, there is no relevance of his opinion in relation to Plaintiff's affirmative claims, and, thus, his opinion in the report ostensibly in support of her affirmative claims does not fit the case.

5. McCullough's opinions on alternative treatment of COVID-19 infection do not fit this case

Dr. McCullough further opines about a protocol for treatment which he participated in creating which involves a complex staging of quarantine, vitamins, zinc, hydroxychloroquine,

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continued contact tracing. Elife. 2021 Apr 26;10:e65534. doi: 10.7554/eLife.65534. PMID: 33899740; PMCID: PMC8195606.

[6] CDC, Clinical Presentation, Clinical considerations for care of children and adults with confirmed COVID-19, , https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/clinical-considerations-presentation.html#:~:text=Asymptomatic%20and%20presymptomatic%20presentation,symptoms%20later%20(presymptomatic%20presentation) (updated December 2023).

ivermectin, and/or other anti-infection agents depending on how symptoms developed. He cites a study which he authored and was published early in the pandemic. Dr. McCullough's protocol involves the administration of ivermectin and hydroxychloroquine, both of which regulatory authorities have determined are not recommended for the treatment of COVID-19. *See* FDA, Why You Should Not Use Ivermectin to Treat or Prevent COVID-19, current as of December 10, 2021, https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19; CDC Ivermectin Products are Not Approved by FDA to Prevent or Treat COVID-19, https://emergency.cdc.gov/newsletters/coca/020122.htm; FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems, https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or. Dr. McCullough's treatment protocol does not meet minimum reliability standards to support an opinion in this case and does not "fit" the affirmative claims which are based upon alleged religious discrimination. While Plaintiff raised issues of genetics in her exemption request, the anti-vaccination opinions and alternative treatment recommendations do not have any probative value in relation to Plaintiff's religious discrimination claims.

6. Dr. McCullough's other anti-vaccination opinions in his first report should be stricken based on unreliability or fit

Dr. McCullough's report includes various other opinions which are no more reliable nor do they "fit" the affirmative case of religious discrimination. These opinions follow what appears to be an anti-vaccination narrative and include the following:

- The vaccines have a dangerous mechanism of action which causes spike protein. His opinions in this regard have been repeatedly rejected by scientists.
- The vaccines are not sufficiently protective against COVID. The goal of the vaccines was to save lives and reduce hospitalizations, which they did with a good overall safety profile.

- The Vaccine Adverse Event Reporting System ("VAERS") reflected numerous adverse events from the vaccine. While VAERS can be useful, it is widely recognized as unreliable as the tip reports to VAERS are not fully investigated and can be manipulated to serve an agenda. *See* CDC, *supra*, Bust Myths and Learn the Facts about COVID-19 Vaccines.

- Natural immunity provides robust immunity making vaccination unnecessary. This view has been repeatedly rejected and is an unreliable generalization.

Given the breadth of Dr. McCullough's report, Defendant retained an expert to rebut many of these broad based and unreliable statements (*see* Report of Dr. Feigl-Ding attached as Exhibit E). This is not, however, a battle of experts as Dr. McCullough's opinions fall so far outside the scientific mainstream and "fit" for this case that the Court should strike them under *Daubert*.

7. McCullough's rebuttal opinions are not reliable or helpful and should be excluded

Dr. McCullough's rebuttal report takes issue with many of Dr. Salmon's opinions but does not undermine the Dr. Salmon's key points relating to undue hardship. Nor does he offer relevant or reliable contrary information. (*See generally* Ex. D). Initially, Dr. McCullough agrees that COVID was a fatal disease primarily for the elderly, even providing a graph that shows that COVID was fatal for approximately 5.5% of the population over age 70. (*Id*. at p. 24). It is unclear what, if anything, Dr. McCullough is attempting to rebut with this statement. Dr. Salmon identified, and Plaintiff agreed during her deposition, that COVID was potentially fatal for vulnerable populations. The Main Line Health system serves vulnerable populations, including the elderly. The experts agree that COVID infections can be fatal to vulnerable populations.

Dr. McCullough criticizes Dr. Salmon's statement regarding asymptomatic transmission. (*Id.* at p. 25). Specifically, Dr. Salmon stated that as of September of 2021 it was well accepted in the scientific community that asymptomatic persons were transmitting COVID-19 and identifies that this type of transmission presented a problem. Consistently, as discussed above, according to

the CDC, transmission from asymptomatic and presymptomatic individuals during the pandemic occurred and presented a substantial risk. Dr. McCullough's attempt to extrapolate broad conclusions contrary to health authorities from a limited data pool are not reliable. Again, Defendant was permitted to rely upon the recommendations and data from public health authorities in formulating policies to protect patients and staff, and Plaintiff's proffered fringe expert opinions do not provide reliable information to help a jury.

Dr. McCullough offers a differing opinion in his rebuttal report to suggest that natural immunity was "robust and durable." (*Id.* at 34). He relies on a study by the Cleveland Clinic following employees earlier in the pandemic, which the Cleveland Clinic acknowledged various study limitations and continued to recommend vaccination. Although some studies show some natural immunity response, there are many studies that showed deficiencies in the natural immunity response. (*Compare* Ex. C at 35-37 with Reports of Dr. Feigl-Ding Ex. E at p. 6 at and Dr. Salmon, Ex. D at p. 8). Importantly, Dr. Salmon cited the contemporaneous CDC study in support of his opinion, as follows:

> A CDC study available in August of 2021 indicated that among previously infected persons, reinfection was about twice as high if not being fully vaccinated, leading CDC to recommend "To reduce their likelihood for future infection, all eligible persons should be offered COVID-19 vaccine, even those with previous SARS-CoV-2 infection."[7]

Dr. McCullough's opinions do not provide any reliable basis to undermine Defendant's decision-making to rely on prevailing public health authority recommendations.

Dr. McCullough further opines that the vaccine is dangerous for individuals who already had COVID. He suggests that there has been "no study demonstrating clinical benefit with

[7] Report of Dr. Salmon at p. 8 citing Centers for Disease Control and Prevention. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021. MMWR. August 13, 2021 / 70(32);1081-1083.

COVID-19 vaccination in those who [had] prior COVID-19 illness."[8] (Ex. D at p. 45). This statement is at best misleading and contrary the many studies showing the benefit of the vaccines and the increased risks of being unvaccinated. (*See*, e.g., Ex. E at 5-6). Putting that aside, as set forth above, the CDC recommended vaccination for those who had previous infection with COVID-19, and Defendant had a right to rely on that advice in the midst of a pandemic, given the Defendant's role as a health care provider to vulnerable populations.

Dr. McCullough further draws an unjustified inference from the CDC response to a FOIA request seeking documents reflecting unvaccinated persons infecting other individuals after recovering from COVID. The CDC Emergency Operations Center responded that this information was not collected. https://www.swfinstitute.org/news/89518/foia-cdc-admits-no-record-of-unvaccinated-person-spreading-covid-after-recovering-from-covid. Dr. McCullough does not identify why he believes this is pertinent or fits the contentions of this case. It does not.

8. McCullough's opinions about gene therapy should be stricken under the qualification, reliability, and fit prongs of Daubert

Dr. McCullough's opinion regarding gene therapy and vaccines are not accurate or supported by any sort of reliable scientific methodology, nor are they relevant to Ms. Gray's exemption request. Dr. McCullough adopts a position contrary to the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) in postulating that the technology employed in COVID-19 vaccines are "gene therapy." He bases this opinion on the following: (1) SEC filings by Moderna and BioNTech in 2018 and 2019 which cite broadly the mRNA therapies have

[8] Dr. McCullough later suggests that Main Line Health "could have provided vaccine exemptions to all employees with proof of prior Covid infection." (p. 47). As noted above, this was not the recommendation of health authorities during the pandemic and there is no scientific or reliable basis for this conclusion. Furthermore, while Dr. McCullough postulates that not every employee needed to vaccinated, he ignores the fact that many of the employees, including the Plaintiff, were treating providers and would come in contact with vulnerable populations. This is in part why the Supreme Court decided that a COVID-19 mandate for health systems was appropriate.

been in the past classified as "gene therapy medicinal products;" (2) information pages from the FDA websites which provide vague definitions of gene therapy which he cherry picks; (3) the CDC's modified definition of "Vaccine" allegedly to address concerns by "pandemic deniers;" and (4) FDA guidance relating to long-term follow up in its regulatory governance of gene therapy products. As discussed below, none of these issues are scientifically reliable bases for calling vaccines gene therapy or provide specialized knowledge helpful to a jury.

First, a manufacturer's assessment of regulatory risk in SEC findings is not a reliable assessment of the science. These hearsay submissions of manufacturers about general risks to investors (submitted to the SEC *before* the COVID vaccines trials were even developed) do not provide any reliable scientific basis to declare that COVID vaccines are gene therapy or gene therapy products. Dr. McCullough's reliance on such vague statements about mRNA technology in pre-pandemic and pre-vaccine SEC filings underscores the lack of supporting evidence after the COVID vaccines were developed.

Second, the FDA treats and regulates mRNA COVID-19 Vaccines as vaccines, not as gene therapy. The FDA has approved the mRNA vaccines as vaccines, not as gene therapy products. *See* FDA News Release, FDA Approves First COVID-19 Vaccine, August 23, 2021, https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine. Furthermore, courts have routinely deferred to the Center for Disease Control ("CDC") on this issue as "the CDC has clearly opined that the [vaccines against COVID-19] constitute 'vaccines.'" *Valdez v. Lujan Grisham*, No. 21-CV-783 MV/JHR, 2022 WL 3577112, at *12 (D.N.M. Aug. 19, 2022)(*citing Messina v. College of New Jersey*, 566 F. Supp. 3d. 236, 248 (D.N.J. 2021). *Accord Smith v. Biden*, 21-cv-19457, 2021 WL 5195688, at *6 (D.N.J. Nov. 8, 2021) (*citing* CDC "Myths

and Facts about COVID-19 Vaccines"). Allowing a fringe expert opinion on a matter that has already been established by public health agencies would not meet the reliability or "fit" criteria.

Dr. McCullough's cherry-picking information from the FDA's informational website in an effort to define vaccines as gene therapy fails to meet generally accepted or reliable standards. The FDA defines "gene therapy" in multiple places, mostly in terms of providing basic information to the public. One cite in McCullough's opinion refers to an FDA informational page which states:

> Human gene therapy seeks to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use.
>
> Gene therapy is a technique that modifies a person's genes to treat or cure disease. Gene therapies can work by several mechanisms:
>
> - Replacing a disease-causing gene with a healthy copy of the gene
> - Inactivating a disease-causing gene that is not functioning properly
> - Introducing a new or modified gene into the body to help treat a disease

What is Gene Therapy?[9] (*See* Ex. A at pp. 13-14).

Curiously, while Dr. McCullough cites this definition for support, it does not support his proposition. Specifically, Dr. McCullough states that "mRNA COVID shots deliver synthetic mRNA with a genetic code that instructs cells to produce a modified form of the SARS-CoV-2 spike protein. In other words, they 'alter the biological properties of living cells for therapeutic use.'" (*Id.* at 14). First, this statement is statement is not true. The vaccines do not "alter the biological properties of living cells." Biological properties of living cells include DNA as well as the cell structure and/or composition. *See* NIH, National Library of Medicine, What is a cell? https://medlineplus.gov/genetics/understanding/basics/cell/. An mRNA vaccine (which is made

[9] https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy#:~:text=Gene%20therapy%20is%20a%20technique,that%20is%20not%20functioning%20properly

from a synthetically derived single mRNA molecule intended to provide temporary instructions for the formation of a spike protein) does not seek to alter biological properties of living cells. The vaccines additionally are prophylactic and not therapeutic, the latter of which is defined as "relating to the *treatment of disease or disorders* by remedial agents or methods." Meriam Webster Dictionary, available at https://www.merriam-webster.com/dictionary/therapeutic. Further, context is important. The FDA goes on to explain that "[g]ene therapy is a technique that modifies a person's genes to treat or cure disease." A gene is the basic physical and functional unit of heredity and is made up of DNA. *See* NIH, National Library of Medicine, "What is a gene?" https://medlineplus.gov/genetics/understanding/basics/gene/ The mRNA vaccines do not modify a person's genes to treat or cure a disease.[10] Additionally, none of the bullet point examples in the FDA informational page apply. The vaccines are not replacing a disease-causing gene with a healthy copy of the gene. The vaccines are not inactivating a disease-causing gene that is not functioning properly. The vaccines are not introducing a new or modified gene into the body to help treat a disease. There is no "gene therapy" (or therapy of genes) happening with Covid vaccines. Dr. McCullough cherry-picks FDA definitions to fit Plaintiff's oxymoronic definition.[11]

[10] The anti-vaccination efforts to call vaccines as gene therapy tend to mislead the public, and thus have been debunked by numerous fact checks and authorities who cited authorities in clarifying that the vaccines did not alter genes. S*ee, e.g.*, Genomics Education Programme, Why mRNA vaccines aren't gene therapies, June 11 2021 available at https://www.genomicseducation.hee.nhs.uk/blog/why-mrna-vaccines-arent-gene-therapies/; Reuters, mRNA vaccines are distinct from gene therapy, which alters recipient's genes, August 10, 2021 available at https://www.reuters.com/article/idUSL1N2PH16N/; GoodRx Health, Are mRNA Vaccines Gene Therapy?, February 23, 2022 available at https://www.goodrx.com/health-topic/vaccines/are-mrna-vaccines-gene-therapy.

[11] Plaintiff's expert pivots to a definition of "gene therapy products" but, again, the FDA does not treat the mRNA vaccines as gene therapy products. Further, the definition of a "gene therapy product" in the Federal Register does not help Plaintiff. The Federal Register defines such products as "containing genetic material administered to modify or manipulate the expression of genetic material or to alter the biological properties of living cells." Federal Register 58, 53097 (Oct. 14, 1993). The vaccines are not administered to modify or manipulate the expression of genetic material. The phrase "modify genetic material" implies an interaction with or modification of the existing DNA, which does not happen with mRNA vaccines. A broader interpretation would have genetic therapy to include food or sleep or any number of things (including flu vaccines) that can have a temporary impact on genetic material and thus credible scientific authorities have focused on therapies that are intended to permanently alter genes/DNA. *See supra* fn 10. Furthermore, even if there is some ambiguity or overlap in the definitions, the FDA has chosen to treat vaccines as vaccines rather than as gene therapy products and deference to the regulatory agency is appropriate.

The overarching consideration here is that the FDA treats the vaccines as vaccines and not gene therapy and that treatment is entitled to deference. A listing of approved gene therapies is provided by the FDA, and it does not include COVID-19 vaccines. FDA, Approved Cellular and Gene Therapy Products, available at https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.

Third, the CDC likewise does not consider the mRNA vaccines as gene therapy for clear scientific reasons. The CDC has repeatedly emphasized that the mRNA does not alter or interact with person's DNA. CDC, Bust Myths and Learn the Facts about COVID-19 Vaccines, available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html. The fact that the CDC may have altered the definition of vaccine slightly because "pandemic deniers" (as Dr. McCullough characterized them) falsely claimed that the vaccines altered a person's DNA does not support Dr. McCullough's opinion.[12] Finally, Dr. McCullough's comment about long-term follow up begs the question of whether the vaccines are human gene therapy which they are not according to the FDA.

In conclusion, there is nothing generally accepted or remotely reliable about Dr. McCullough's opinions on gene therapy nor is it relevant. Plaintiff's exemption request included her pastor's statement reflects that she has "personal convictions" about the function of the vaccine which she believes changes her genetic make up. Dr. McCullough should be precluded from offering any opinion on gene therapy in relation to Plaintiff's views as they do not meet the *Daubert* reliability or fit standards.

[12] Dr. McCullough's report contains various other references in support of his views, including inarticulate descriptions of vaccines in newspapers. None of these references appear credible, reliable, or worthy of consideration or extensive analysis.

9. McCullough does not offer reliable or qualified rebuttals to Dr. Salmon

After denunciating vaccination mandates and self-promoting his opinions of what he would have done better than the CDC, Dr. McCullough provides "Counterpoints to Dr. Salmon's summary." In response to Dr. Salmon's statement that health care staff in a health care setting were at increased risk of serious disease and death, Dr. McCullough states that COVID-19 was most likely to spread at home.[13] Even if true, the statement does not undermine Dr. Salmon's opinion that healthcare workers were at an increased risk. Dr. Salmon identified that the prevalence of COVID infection among healthcare workers in 2020 was 11%, more than the general population. Dr. Salmon based his opinions on the spread of COVID-19 with regard to healthcare workers on three contemporaneously relevant publications specifically studying occupational exposure of COVID-19 in relation to healthcare workers, including an article published in the American Journal of Epidemiology. Dr. McCullough cited news articles with mostly anecdotal comments about the spread of COVID in households, and a quote from one hospital representative that most of their cases were from community spread. Dr. McCullough's comments otherwise do not provide a reliable counterpoint to Dr. Salmon's opinion. Nor do they meet *Daubert* standards.

[13] Interestingly, Dr. Salmon cites a CNN and an ABC news articles published in 2020 for his information about household spread. The ABC news article, published in December of 2020, noted that 70% of new cases were spread through households *and* small gatherings. The actual studies about household spread, after vaccination, found that spread in households with vaccinated individuals were about 40-50% lower. *See* Harris RJ, Hall JA, Zaidi A, Andrews NJ, Dunbar JK, Dabrera G. Effect of vaccination on household transmission of SARS-CoV-2 in England. N Engl J Med 2021; doi: 10.1056/NEJMc2107717. Another study found that alternative measures to vaccination were inadequate in closed spaces such as households and concluded "[w]hile masking, physical distancing, and quarantining the whole household may reduce or prevent transmission beyond the household, these strategies are less effective within the household, especially in the setting of high viral load infections and crowded living spaces. Frequent point-of-care testing and post-exposure prophylaxis in those at risk for severe illness and ultimately widespread and equitable *distribution of vaccines* are needed to lessen the impact of COVID-19 within households and vulnerable communities." Carla Cerami et al., Household Transmission of Severe Acute Respiratory Syndrome Coronavirus 2 in the United States: Living Density, Viral Load, and Disproportionate Impact on Communities of Color, 74 CLINICAL INFECTIOUS DISEASES 1776 (2022), https://doi.org/10.1093/cid/ciab701.

Dr. McCullough goes on to summarize his point on natural immunity, which is addressed above, and has been rejected before. He contends that there was no objective way to limit exceptions to the COVID-19 mandate to individuals with sincerely held religious beliefs because he believes MLH based decisions on indefensible science positions. Again, to the extent Dr. McCullough is speaking about religion, he is not qualified. To the extent he is speaking about science, most of his opinions on COVID vaccines or gene therapy have been previously addressed as unreliable and unhelpful. He believes that if MLH granted religious exemptions to every person who submitted requests, high vaccination levels could have been achieved. MLH developed a vaccine policy and applied it in good faith to protect patients and staff from a deadly disease. Dr. McCullough's *ipse dixit* assertions and speculation do not undermine Dr. Salmon's opinion that every unvaccinated healthcare worker presented additional risk.

In all, Dr. McCullough's rebuttal report presents an antivaccination narrative. He delves into debunked herd immunity arguments, which subset of the population vaccination helped, how fast COVID vaccines were developed and clinical contraindications to the vaccine. He twists study data to support his deterministic opinion that his approach was better than the government agencies. Almost all of Dr. McCullough's opinions are contrary to the CDC recommendations and information provided to health systems at the time of the pandemic.[14] None of his report undermines the hardships facing health systems trying to protect patients during a deadly pandemic who relied upon the CDC's evolving recommendations. The Supreme Court affirmed the CMS

[14] The CDC provided information throughout the pandemic which supported that the vaccines were safe and effective. The latest CDC information about the vaccine is available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html. The CDC states that "COVID 19-vaccines are effective at protecting people from getting seriously ill, being hospitalized, and dying. Vaccination remains the safest strategy for avoiding hospitalizations, long-term health outcomes, and death." *Id.* The CDC addressed efforts at spreading misinformation about COVID at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html. As noted above, the Defendant relied upon the CDC and had a right to do so. Dr. McCullough's report attempts to attack the CDC based upon limited data or inferences drawn from studies which were not drawn by the study authors.

vaccine mandate in *Biden v. Missouri*, *supra,* and Dr. McCullough's opinions are contrary to reliable authority and are not helpful if a jury is required.

III. CONCLUSION

Plaintiff claims that the denial of an exemption from the COVID-19 Vaccination Policy constitutes religious discrimination. Plaintiff stated in her exemption request that the COVID-19 vaccinations affected her genes and submitted a report from her pastor that she feared they would alter her genetic make up. She offers experts with dubious opinions, including a cardiologist, who offers legal conclusions and irrelevant anti-vaccination opinions. These expert opinions, however, are unreliable and unhelpful to any jury determination of the case. The Defendant followed regulatory authorities who followed the science. The decision to impose a vaccination mandate has been upheld at the highest regulatory and legal authorities in this country and this Court has discretion to follow those decisions and exercise its gatekeeping function in excluding unreliable, unfit and/or unqualified opinions to the contrary.

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